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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,215	03/12/2004	Daniel Rohleder	WP 21723 US	8547
7590	07/21/2006		EXAMINER	
Sujatha Subramaniam Roche Diagnostics Operations, Inc. 9115 Hague Road, Bldg. D Indianapolis, IN 46250			LIN, JACK	
		ART UNIT	PAPER NUMBER	3768

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,215	ROHLEDER ET AL.	
	Examiner Jack Lin	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12 March 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/12/2004.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on March 12, 2004 is acknowledged. The references listed therein have been considered.
2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

In particular WO 98/55850 (page 7, paragraph 23); H. Martens et al. (page 12, paragraph 55), and A. Hoskuldsson (page 12, paragraph 55) are not listed on the IDS.

Claim Objections

3. Claims 1, 3, and 7 are objected to because of the following informalities:
Regarding Claim 1, "includes" in line 11 should be omitted,
Regarding Claim 3, the comma (,) in line 3 should be omitted,
Regarding Claim 7, "os" is misspelled and should be replaced with "is".
Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5, 8, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation "at most 900 nm", and the claim also recites "preferably at most 800 nm, especially preferably at most 600 nm" which is the narrower statement of the range/limitation. Also, claim 8 recites the broad recitation "at most 50 kDa", and the claim also recites "preferably at most 20 kDa" which is the narrower statement of the range/limitation. Also, claim 20 recites the broad recitation "at most 2 mm", and the claim also recites "preferably

at most 1 mm and especially preferably at most 0.5 mm" which is the narrower statement of the range/limitation.

6. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The wording of Claim 12 makes it unclear as to what is being claimed. In particular, it is unclear how the "reflective surface" affects "the primary light beam emerging from the light irradiation surface" and the "detection range detected by the detection light guide."

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 is non-statutory as it improperly includes body parts as part of the claimed invention (See Claim 1 – "inserted through the skin surface into the skin" and "pierces the skin"). The claim should recite "adapted to be inserted through the skin surface into the skin" and "adapted to be pierce the skin." ~

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5, 9-10, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al. (International Application WO 02/07585 A2). Ward et al. discloses the same invention including a device for determining the concentration of an analyte. Ward et al. discloses a measurement device comprising a light source (page 22, lines 11-12), a fiber optic probe that can be inserted into a tissue bed (page 19, lines 15-16), a charge couple device (page 22, lines 12-13), and a signal analyzer (page 23, line 25) used to produce Raman spectroscopy results (page 25, line 12) of analytes including glucose (page 25, line 17).

Regarding Claim 3, Ward et al. discloses testing interstitial fluid (page 19, lines 20-21).

Regarding Claims 4 and 5, Ward et al. discloses using a light of one wavelength (page 22, line 18) with wavelengths less than 600 nm (page 22, line 20).

Regarding Claims 9 and 10, Ward et al. discloses probe of a fiber optic bundle configured with one emitting fiber in the center surrounded by collection fibers (page 22, lines 22-23).

Regarding Claim 20, Ward et al. discloses the probe to be less than 0.2 mm (page 23, line 4).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. as applied to Claim 1 above, and further in view of Caro (US Patent 5,348,003). Ward et al. discloses the invention substantially as claimed including a device for determining the concentration of an analyte. Ward et al. does not show using a multivariate analysis method for determining the concentration of the analyte from a Raman spectrum. However, Caro discloses a computer that uses a variety of algorithms including multivariate analysis techniques (column 14, lines 3-9) to determine the concentration of glucose (column 4, line 41) from a Raman spectrum (column 9, line 66). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have provided the analyte concentration determining device of Ward et al. with a processor that uses multivariate analysis techniques to determine the concentration of glucose from a Raman spectrum as taught by Caro since Ward et al. teaches using a computing arrangement and Caro teaches one known arrangement suitable for use with the device of Ward et al.

13. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. as applied to Claim 1 above, and further in view of Haar et al. (PCT Application WO 99/07277) which corresponds to Haar et al. (US Patent 6,584,335 B1). This office action refers to the US Patent for the purpose of referencing the prior art but uses the PCT application publication date. Ward et al. discloses the invention substantially as claimed including a device for determining the concentration of an analyte. Ward et al. does not show enclosing the sensor head with a semipermeable membrane. However, Haar et al. teaches enclosing a fiber optic probe with a semipermeable membrane (column 5, line 27-30) that has a cut off of 1000 Da (column 5, line 33) in order to avoid protein deposits on the light guide and other interfering

effects associated with large molecules in the interstitial liquid. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have provided the analyte concentration determining device of Ward et al. with a semipermeable membrane covering the fiber optic probe as taught by Haar et al. in order to avoid the interfering effects associated with large molecules in the interstitial liquid.

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. as applied to Claim 9 above, and further in view of Bernsee (US Patent 3,966,300). Ward et al. discloses the invention substantially as claimed including a device for determining the concentration of an analyte. Ward et al. teaches an arrangement that includes an emitting fiber surrounded by collection fibers but does not show forming a detection light guide ring from a fiber optic tube. However, Bernsee teaches enclosing a fiber optic with a fiber optic sheath (figure 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have provided the analyte concentration determining device of Ward et al. with a detection light guide ring formed from a fiber optic sheath as taught by Bernsee since it has generally been held to be within the skill level of the art to modify a device with alternate equivalent expedients.

15. Claims 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. as applied to Claim 1 above, and further in view of Wach et al. (US Patent 6,370,406 B1). Claim 12 is viewed with the best current understanding of the claim in light of the 112-2nd paragraph rejection as detailed above. Ward et al. discloses the invention substantially as claimed including a device for determining the concentration of an analyte. Ward et al. only shows the details of one configuration of the fiber optic probe but teaches other configurations may be used (page 22,

lines 23-30). Wach et al. discloses a fiber optic bundle with a pencil-point tip having a 40 degree angle (column 29, lines 15-16, figure 27A) with the end faces coated with internally reflective metallic film (column 29, lines 21-22) resulting in a probe with excellent performance for Raman spectroscopy (column 29, lines 15-16). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to have provided the analyte concentration determining device of Ward et al. with the fiber optic probe configurations as taught by Wach et al. in order to have light management with excellent performance for Raman spectroscopy.

Regarding Claims 16, Wach et al. discloses another embodiment with an end-piece that is conically shaped and has a central recess (figure 41).

Regarding Claims 17-19, Wach et al. discloses another embodiment with an end-piece that is separated from the center fiber (column 38, lines 10-11 and figure 40A) thus forming a reflecting sleeve. Wach et al. also discloses having an angle of 10 degrees (column 29, line 19).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Iyer et al. (US Patent 4,925,268) discloses a fiber-optic sensor covered with a analyte permeable membrane.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack Lin whose telephone number is (571) 272-7694. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL
Art Unit 3768

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PRIMARY EXAMINER